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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,664	01/16/2002	Dan E. Fischer	7678.567	6069
22913	7590	12/28/2004	EXAMINER	
WORKMAN NYDEGGER (F/K/A WORKMAN NYDEGGER & SEELEY)			CHIN, BRAD Y	
60 EAST SOUTH TEMPLE			ART UNIT	
1000 EAGLE GATE TOWER			PAPER NUMBER	
SALT LAKE CITY, UT 84111			1744	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/050,664	FISCHER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Brad Y. Chin	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 January 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>22 March 2002</u> . | 6) <input type="checkbox"/> Other: _____  |

DETAILED ACTION

***Specification***

The disclosure is objected to because of the following informalities: On page 11, line 19, the word, "raises" should be amended to "raised."

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-4 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hahn [U.S. Patent No. 6,139,320].

Regarding claim 1, Hahn teaches a method for disinfecting a root canal during an endodontic procedure, comprising:

providing access to a root canal of a tooth (dental angled hand piece 10 with ultrasonic vibration generator 16, ultrasonic deflecting head 28, and tool 36 for providing access to a root canal of a tooth – See Fig. 3; claim 65 – a method of forming a cavity in a tooth comprising the steps of obtaining and using an apparatus according to claim 1 to form the cavity); and

introducing a viscous disinfecting composition into the root canal, wherein the viscous disinfecting composition is able to adhere to walls of the root canal so as to enable the disinfecting composition to disinfect the root canal (See Specification, col. 8, lines 9-39 - introduction of viscous disinfecting composition, comprising sodium hypochlorite – for dissolving remnants of soft tissue, e.g. during the preparation of endodontic cavities; water – "slurry"; and a

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gelling agent – gels of glycerine or gelatine, into the root canal, where the addition of aerosiles changes the viscosity of the gels, providing for the ability of the disinfecting composition to overcome gravity, making it possible to renounce continuous supplies of the disinfecting composition, i.e. allowing the viscous disinfecting composition to adhere to the walls of the root canal so as to enable the disinfecting composition to disinfect the root canal area).

Regarding claim 2, Hahn teaches the method as defined in claim 1, wherein the viscous disinfecting composition comprises sodium hypochlorite, water, and a gelling agent (See Specification, col. 8, lines 9-39 – viscous disinfecting composition comprises sodium hypochlorite, water, e.g. for the slurry, and a gelling agent, e.g. glycerine or gelatine or 1 to 10% chloro-hexidine-digluconate-gel).

Regarding claim 3, Hahn teaches the method as defined in claim 2, wherein the gelling agent comprises at least one finely divided particulate gelling agent (See Specification, col. 8, lines 9-23 – in addition to the aqueous suspensions generally gel-like grain slurries of abrasive particles, e.g. granulates which at least partly contain silicates or are silanized, and/or fine grain particles. The gelling agent further comprises a thickening agent, aerosiles, making the gel more viscous and providing for the ability to overcome gravity, e.g. to adhere to the walls of the root canal).

Regarding claim 4, Hahn teaches the method as defined in claim 3, wherein the finely divided particulate gelling agent comprises at least one of fumed silica or fumed aluminum oxide (See Specification, col. 8, lines 9-23 – in addition to the aqueous suspensions generally gel-like grain slurries of abrasive particles, e.g. granulates which at least partly contain silicates or are silanized, and/or fine grain particles. The gelling agent further comprises a thickening agent, aerosiles – a suitable fumed silica gelling agent, making the gel more viscous and allowing the ability to overcome gravity, e.g. to adhere to the walls of the root canal).

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Regarding claim 20, Hahn teaches a method for disinfecting a root canal during an endodontic procedure, comprising:

providing access to a root canal of a tooth (dental angled hand piece 10 with ultrasonic vibration generator 16, ultrasonic deflecting head 28, and tool 36 for providing access to a root canal of a tooth – See Fig. 3; claim 65 – a method of forming a cavity in a tooth comprising the steps of obtaining and using an apparatus according to claim 1 to form the cavity); and

introducing a viscous disinfecting composition into the root canal comprising sodium hypochlorite, water, and a gelling agent (See Specification, col. 8, lines 9-39 - introduction of viscous disinfecting composition, comprising sodium hypochlorite – for dissolving remnants of soft tissue, e.g. during the preparation of endodontic cavities; water – “slurry”; and a gelling agent – gels of glycerine or gelatine, into the root canal).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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2. Claims 13, 17-19, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn.

Hahn teaches the method for disinfecting a root canal during an endodontic procedure as defined in claim 1 above.

Regarding claim 13, Hahn fails to teach the method where the viscous disinfecting composition is left in the root canal for a time in a range of about 1 minute to about 1 hour.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the appropriate amount of time that the viscous disinfecting composition of Hahn should be left in the root canal during such an endodontic procedure. Use of sodium hypochlorite is a common disinfectant in endodontic procedures and thus one of ordinary skill in the art, without undue experimentation, would be able to determine that leaving the viscous disinfecting composition of Hahn in the root canal for a time ranging from about 1 minute to about 1 hour would be appropriate to disinfect the bacteria in the root canal.

Regarding claims 17-19 and 22-23, Hahn further fails to teach the method where the viscous disinfecting composition has a pH in a range from about 8 to about 12.5 [claim 17]; from about 10 to about 12 [claim 18 and claim 22]; and from about 11 to about 11.5 [claim 19 and claim 23].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the viscous disinfecting composition of Hahn with a pH in the ranges defined in claims 17-19 and 22-23. It is well known that sodium hypochlorite is typically more stable with a higher pH, e.g. a more basic pH. It is also well known that gel stability decreases with a higher pH. Accordingly, it would have been obvious to one of ordinary skill in the art to determine, without undue experimentation, the appropriate pH for the viscous disinfecting composition. It is also well known that to buffer a composition's pH to be more basic, one would

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add a mild or strong base or other pH adjuster. Accordingly, use of such a base or pH adjuster would allow one to alter the pH levels of Hahn's viscous disinfecting composition to those claimed in claims 17-19 and 22-23 and provide an appropriate pH level for use in such an endodontic procedure.

Regarding claim 21, Hahn teaches the method according to claim 17, as previously explained, where the gelling agent comprises fumed silica (See Specification, col. 8, lines 9-23 – in addition to the aqueous suspensions generally gel-like grain slurries of abrasive particles, e.g. granulates which at least partly contain silicates or are silanized, and/or fine grain particles. The gelling agent further comprises a thickening agent, aerosiles – a suitable fumed silica gelling agent, making the gel more viscous and allowing the ability to overcome gravity, e.g. to adhere to the walls of the root canal).

3. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Clay [U.S. Patent No. 6,413,499].

Hahn teaches the method for disinfecting a root canal during an endodontic procedure as defined in claim 1 above.

Hahn fails to teach the method, where the gelling agent comprises at least one polymeric gelling agent or where the gelling agent comprises carboxypolymethylene.

Regarding claim 5, Clay teaches a method where the gelling agent, which has a viscosity such that the composition may adhere to and remain in place when applied is mixed with water, where the gelling agent comprises at least one polymeric gelling agent, e.g. polyalkylene glycol, polypropylene glycol, etc. (See Specification, col. 9, lines 52 to col. 10, line 5).

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Regarding claim 6, Clay teaches a method where the gelling agent, which has a viscosity such that the composition may adhere to and remain in place when applied is mixed with water, where the gelling agent comprises carboxypolymethylene (See Specification, col. 9, lines 52 to col. 10, line 5).

Clay further teaches "whereas the liquid carrier is superior in terms of the rate and extent of penetration and absorption of the active agents, the gel carrier is superior in terms of tissue adhesion and the ability to remain where initially placed (See Specification, col. 10, lines 7-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Clay with Hahn because Hahn teaches the importance of the ability of the gelling agent to overcome gravity, e.g. adhere to the walls of the root canal, making it possible to renounce continuous supply of the aqueous solution and evacuation thereof. Gelling agents with at least one polymeric gelling agent are common in the art. It would have been obvious to include a gelling agent, which comprises at least one polymeric gelling agent, and more particularly the gelling agent, carboxypolymethylene as a thickener for the disinfecting composition.

4. Claims 7-10 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Lee et. al. [U.S. Patent Publication No. 2002/0192627]

Hahn teaches the method for disinfecting a root canal during an endodontic procedure as defined in claims 1 and 2 above.

Regarding claims 7-10, Hahn fails to teach the method where the sodium hypochlorite is included in a range of about 0.01% to about 50% [claim 7]; about 0.1% to about 40% [claim 8]; about 1% to about 20% [claim 9]; and about 1% to about 20% [claim 10] by weight of the viscous disinfecting composition.



Lee teaches a dental training device where the viscous disinfecting composition comprises sodium hypochlorite and other constituents in the range from about 1 to 80% by weight (See Specification, col. 6, [0057]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lee with Hahn because it would have been obvious to formulate a viscous disinfecting composition comprising sodium hypochlorite in the ranges defined in claims 7-10 with other constituents, without undue experimentation, to provide a suitable disinfectant concentration for disinfecting and sanitizing the root canal during such an endodontic procedure.

Regarding claim 25, Hahn teaches a method for disinfecting a root canal during an endodontic procedure, comprising:

providing access to a root canal of a tooth (dental angled hand piece 10 with ultrasonic vibration generator 16, ultrasonic deflecting head 28, and tool 36 for providing access to a root canal of a tooth – See Fig. 3; claim 65 – a method of forming a cavity in a tooth comprising the steps of obtaining and using an apparatus according to claim 1 to form the cavity); and

introducing a viscous disinfecting composition into the root canal, comprising sodium hypochlorite, water, and fumed silica (See Specification, col. 8, lines 9-39 - introduction of viscous disinfecting composition, comprising sodium hypochlorite – for dissolving remnants of soft tissue, e.g. during the preparation of endodontic cavities; water – “slurry”; and a gelling agent. The gelling agent further comprises a thickening agent, aerosiles – a suitable fumed silica gelling agent, making the gel more viscous and allowing the ability to overcome gravity, e.g. to adhere to the walls of the root canal).

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Hahn does not teach the method where the viscous disinfecting composition comprises sodium hypochlorite in an amount in a range of about 1% to about 20% by weight, water, and fumed silica in an amount in a range of about 1% to about 10% by weight.

As previously identified, Lee teaches a dental training device where the viscous disinfecting composition comprises sodium hypochlorite and other constituents in the range from about 1 to 80% by weight (See Specification, col. 6, [0057]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lee with Hahn because one of ordinary skill in the art could, without undue experimentation, have formulated a viscous disinfecting composition, comprising sodium hypochlorite in an amount ranging from about 1% to about 20% (within the range of Lee's teachings), to properly disinfect and sanitize the root canal; water, to create the slurry; and the gelling agent, fumed silica – as identified above – in an amount ranging from about 1% to about 10%, to provide the appropriate viscosity for the disinfecting composition to adhere to the walls of the root canal, for such an endodontic procedure.

Regarding claims 26 and 27, it would accordingly have been obvious to provide for a method where the viscous composition further includes a base in an amount so that the pH of the composition is in a range of about 10 to about 12 and more particularly about 11 to about 11.5 (See explanation for claims 18-19 and 22-23 respectively above).

5. Claims 11-12 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Nance [U.S. Patent No. 6,638,064].

Hahn teaches the method for disinfecting a root canal during an endodontic procedure as defined in claim 1 above.

Hahn fails to teach the method according to claim 1 further comprising cleaning at least one part of the root canal with an endodontic tool; and irrigating the root canal to remove the viscous disinfecting compound and any loosened pulp or other debris.

Regarding claims 11 and 12, Nance teaches a method for irrigating a root canal and an endodontic apparatus for use in performing root canal therapy on a tooth, which is particularly useful for irrigating a root canal possessing a non-linear central axis.

Nance teaches that endodontics or root canal therapy is a well-known procedure where a series of very delicate flexible, rotary driven or finger-held instruments or files (endodontic tools) are used to extirpate or clean out and shape the root canal (See Specification, col. 1, lines 17-19). Because the instruments or files are incapable of removing all of the necessary tissue and debris, the endodontic procedure is followed with removal of tissues and debris trapped in the smaller lateral canals extending off the main root canal by irrigating the root canal with an injection of disinfecting composition, such as a typical disinfecting fluid in a dilute solution of sodium hypochlorite (See Specification, col. 1, lines 27-35). Accordingly, Nance teaches a flexible endodontic tool, which comprises an endodontic file (elongate shank 10 having a first end 12 and an opposite end of the shank 14, which may be angled or pointed if needed for a particular application, e.g. breaking up pulp or infected tissue in the root canal) and where the viscous disinfecting composition is introduced into the root canal by means of the endodontic file (See Fig. 1; See Specification, col. 3, lines 48-55 and col. 6, lines 9-31, respectively).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Nance with Hahn's method because Hahn teaches an apparatus and method for disinfecting a root canal during an endodontic procedure, where the endodontic tool comprises numerous tools attached to the endodontic tool. It would have been obvious to include in Hahn the ability to clean at least a part of the root canal with the

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endodontic tool and subsequently irrigate the root canal to remove the viscous disinfecting composition and any loosened pulp or other debris after a predetermined period of time.

Regarding claim 24, it accordingly would have been obvious to combine the teachings of Nance with Lee to define a method according to claim 17, as described above, where the method further comprises cleaning at least part of the root canal with an endodontic tool and irrigating the root canal to remove the viscous disinfecting composition and any loosened pulp or other debris.

6. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Dickson et. al. [U.S. Patent No. 5,593,458].

Hahn teaches the method for disinfecting a root canal during an endodontic procedure as defined in claim 1 above.

Hahn fails to teach the method where the viscous disinfecting composition has a viscosity in a range from about 500 cps to about 20,000 cps [claim 14]; about 5,000 cps to about 100,000 cps [claim 15]; and 10,000 cps to about 50,000 cps [claim 16].

Dickson teaches that a gel may be made in a variety of ways, but the gel used will typically substantially cling to a vertical surface and has a preferred viscosity range. Dickson teaches that by varying the amount of gelling or thickening agent, the viscosity resulting from the mixture in this particular invention would preferably be between 6,500 and 50,000 cps as measured in a 600 ml beaker using a Brookfield Model RD Viscometer (See Specification, col. 3, lines 24-32).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Dickson with Hahn because it is well known in the art and supported in Dickson that a gelling agent allows a user to alter the viscosity of an aqueous

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composition. Accordingly, it would have been obvious to use a gelling agent to formulate a viscous disinfecting composition with a desired viscosity in the ranges defined in claims 14-16, without undue experimentation, providing a suitable viscous disinfectant composition that adheres to the walls of a root canal during such an endodontic procedure.

### ***Conclusion***

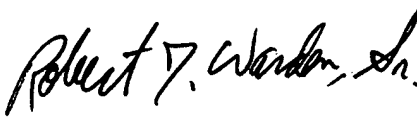
7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Y. Chin whose telephone number is 571-272-2071. The examiner can normally be reached on Monday – Friday, 8:00 A.M. – 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden, can be reached at 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

byc  
December 23, 2004

  
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